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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,800	07/09/2007	Hongyue Dai	9301-251-999	3177

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JONES DAY  
222 EAST 41ST ST  
NEW YORK, NY 10017

EXAMINER
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SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

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03/03/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,800	<b>Applicant(s)</b> DAI ET AL.	
	<b>Examiner</b> Carolyn Smith	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 29,42,45,48,54,58-67,89,90 and 92-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29,42,45,48,54,58-67,89,90 and 92-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07092007,02272009</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's election of Group II (claims 29, 42, 43, 45, 48, 54, 58-67, and 89-104) and new claim 105 (now in Group II), filed 12/15/09, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in this portion of the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant elected a selection of a combination of genes with traverse in the second portion of the restriction requirement; however, this portion of the restriction requirement is hereby withdrawn due to persuasive arguments.

Drawings, filed 9/5/06, have been accepted by the Examiner.

The information disclosure statements, filed 07/09/2007 and 02/27/2009, have been considered by the Examiner.

Claims herein under examination are 29, 42, 45, 48, 54, 58-67, 89-90, and 92-105.

### ***Specification***

The specification is objected to because of the following issues:

The use of the trademarks (i.e. Mathematica, page 85) has been noted in this application. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

***Claim Rejections-35 USC § 112, First paragraph***

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 42, 45, 48, 54, 58-67, 89-90, and 92-105 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assigning a human breast cancer patient to a one of a plurality of categories based on status of prognosis using the specific markers as listed in Tables 1-5 of the specification as well as predicting a human breast cancer patient as having a good or poor prognosis, does not reasonably provide enablement for assigning a non-human breast cancer patient based on status of prognosis using the specific markers as listed in Tables 1-5 of the specification, and predicting the prognosis of a non-human breast cancer patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

**LACK OF SCOPE OF ENABLEMENT**

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the

Art Unit: 1631

prior art; (g) the breadth of the claims; and (h) the relative skill in the art. The factors are analyzed for the instant case as follows:

(a) In the instant case, the amount of experimentation required by the skilled artisan in order to practice of assigning a non-human breast cancer patient to one of a plurality of categories in a clinical trial based on status of prognosis using the specific markers as listed in Tables 1-5 of the specification, and predicting a prognosis of the non-human breast cancer patient would require an unpredictable amount of experimentation for the following reasons:

(b) The claims are drawn to a method of assigning a breast cancer individual/patient to one of a plurality of categories based on status of prognosis using the specific markers as listed in Tables 1-5 of the specification, and predicting a prognosis of the patient. The specification does not provide an explicit definition for the term “patient.” The term is defined in the dictionary as “an individual awaiting or under medical care and treatment” (see Merriam-Webster On-line: <http://www.m-w.com/cgi-bin/dictionary>), and the same dictionary defines the term “individual” as “(1a): a particular being or thing as distinguished from a class, species, or collection.” Thus, the term “breast cancer patient” recited in the claim is reasonably interpreted as including non-human individuals. The markers listed in Tables 1-5 of the specification, however, appear to be human markers, such as NM\_000599 (SEQ ID NO:51) and NM\_002205 (SEQ ID NO:93), and are for assigning human breast cancer patients based on prognosis using the markers and predicting a prognosis of the patients based on the classification. There is no guidance in the instant specification that teaches the skilled artisan how to use these human markers to assign non-human breast cancer patients to categories and predict prognosis these patients based on the classification.

Art Unit: 1631

(c) The instant application does not present any working examples wherein the human markers as listed in Tables 1-5 are used to assign non-human breast cancer patients based on prognosis using the markers and predict the prognosis of the patients based on the classification.

(d)-(f) The nature of the invention -- a method of assigning a breast cancer patient to a category based on status of prognosis using the specific markers as listed in Tables 1-5 of the specification, and predicting the prognosis of the patient -- is complex. It would have been known in the art that genes involved in human breast cancer are not the same in human and non-human organisms such as mouse. For example, Casey (IDS document: Current Opinion in Oncology, 1997, Vol. 9, pages 88-93) discloses that the human breast tumor suppressor BRCA-1 only shares 58% identity with its mouse counterpart. See page 89, right column. Further, and more significantly, the markers as listed in Tables 1-5 are not the same between human and non-human organisms. Thus, using a human marker for assigning non-human breast cancer patients and predicting a prognosis is highly unpredictable.

(g)-(h) The claims to a method of assigning a breast cancer individual/patient based on status of prognosis using the specific markers as listed in Tables 1-5 of the specification, and predicting the prognosis of the patient are broad especially because the individuals with breast cancer can be any non-human animals or other organisms. The level of skill of those in the art who practice using the method to assign a breast cancer individual/patient based on status of prognosis using the specific markers as listed in Tables 1-5 of the specification, and predict the prognosis of the patient is high.

The skilled practitioner would first turn to the instant specification for guidance in practice of using the method to assign a breast cancer individual/patient based on status of

Art Unit: 1631

prognosis using the specific markers as listed in Tables 1-5 of the specification, and predict the prognosis of the patient. However, the specification does not provide sufficient guidance of doing such. As such, the skilled practitioner would turn to the prior art for such guidance.

However, the prior art does not teach such a method. Finally, said practitioner would turn to trial and error experimentation for using the markers to assign a breast cancer individual/patient based on status of prognosis using the specific markers as listed in Tables 1-5 of the specification, and predict the prognosis of the patient without sufficient guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 42, 45, 48, 54, 58-67, 89-90, and 92-105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 29 (steps a and b), 42 (steps a and b), 58-67, 89 (classifying step), and 95-104 recite commas which lack clarity. It is unclear if Applicant intends these commas to mean “and”, “or”, or “and/or”. Clarification of this issue via clearer claim wording is requested.

Art Unit: 1631

Claims 45, 48, 54, 90, 92-94, and 105 are also rejected due to their dependency from claims 29, 42 and 89.

Claims 29 (lines 33, 36), 42 (lines 18, 21), and 89 (lines 19, 22) recite “representative of” which is vague and indefinite because the limitation does not clearly delineate what criteria and to what degree the criteria must be met to be considered a representation of the plurality of patients with the good or bad outcomes. Clarification of this issue via clearer claim wording is requested. Claims 45, 48, 54, 58-67, 90, and 92-105 are also rejected due to their dependency from claims 29, 42 and 89.

### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29, 42, 45, 48, 58, 60, 89, 90, 92, 93, 95, 97, and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Dai et al. (US 2004/0058340 A1).

Art Unit: 1631

Dai et al. disclose a computer-implemented method for assigning an individual having breast cancer to one of a plurality of categories in a clinical trial as well as predicting a good or bad prognosis (abstract, 0014, 0021) by classifying ER-, sporadic versus BRCA1, etc. (0003, 0012-0016, 0025) determining a profile comprising measurements of expression levels from 2 genes as well as transcript levels (i.e. AF055033, NM\_000599; AF005487, Contig50728\_RC, Contig53598\_RC, NM\_002888, NM\_005218, U17077) (0013-0016, 0025, 0034, 0090-0092, 0119, Table 1), classifying an individual as having good or poor prognosis (0014, 0026) via comparing similarities to templates above or below a threshold with templates based on levels from good or bad outcome patients (i.e. non-reoccurrence vs. reoccurrence of metastases) (0003, 0026-0029, 0131-0148, 0328-0329), and assigning to one category in a clinical trial if the individual has a good prognosis and to a second category if the individual has a poor prognosis (abstract, 0021), as stated in instant claims 29, 42, 45, 58, 60, 89, 90, 92, 95, 97, as well as using average expression levels (0027, 0052, 0064, 0157, 0329), as stated in instant claims 48, 93, and 105.

Thus, Dai et al. anticipate instant claims 29, 42, 45, 48, 58, 60, 89, 90, 92, 93, 95, 97, and 105.

### ***Conclusion***

No claim is allowed.

Art Unit: 1631

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

February 25, 2010

/Carolyn Smith/  
Primary Examiner  
AU 1631

Application/Control Number: 10/591,800

Page 10

Art Unit: 1631